Complete Summary

GUIDELINE TITLE

VA/DoD clinical practice guideline for management of outpatient chronic obstructive pulmonary disease.

BIBLIOGRAPHIC SOURCE(S)

Management of COPD Working Group. VA/DoD clinical practice guideline for the management of outpatient chronic obstructive pulmonary disease. Washington (DC): Department of Veteran Affairs, Department of Defense; 2007. 138 p.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Veterans Health Administration (VHA). Clinical practice guideline for the management of chronic obstructive pulmonary disease. Version 1.1a. Washington (DC): Department of Veterans Affairs (U.S.), Veterans Health Administration; 1999 Aug. 116 p.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse (NGC): This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- July 08, 2008, Fluoroquinolones (ciprofloxacin, norfloxacin, ofloxacin, levofloxacin, moxifloxacin, gemifloxacin): A BOXED WARNING and Medication Guide are to be added to the prescribing information to strengthen existing warnings about the increased risk of developing tendinitis and tendon rupture in patients taking fluoroquinolones for systemic use.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Chronic obstructive pulmonary disease (COPD)

Note: The guideline does not cover the management of asthma, bronchopulmonary dysplasia, and bronchiectasis.

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Emergency Medicine
Family Practice
Internal Medicine
Pharmacology
Pulmonary Medicine

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians
Respiratory Care Practitioners

GUIDELINE OBJECTIVE(S)

- To describe the critical decision points in outpatient, emergency, and inpatient management of chronic obstructive pulmonary disease (COPD)
- To provide a clear and comprehensive guideline incorporating current information and practices for practitioners throughout the Department of Defense (DoD) and Veterans Health Administration systems.
- To improve local management of patients with COPD and improve patient outcome
- To reduce current practice variation and provide facilities with a structured framework to improve patient outcomes
- To provide evidence-based recommendations to assist providers and their patients in selecting the optimal choices in the decision-making process for the management and care for COPD

- To establish priorities for future research that are lacking in this field
- To develop outcome measurements to generate practice-based evidence that can ultimately be used to improve clinical guidelines

TARGET POPULATION

Adults with suspected or confirmed chronic obstructive pulmonary disease (COPD) who are eligible for care in the Veterans Administration (VA) or Department of Defense (DoD) health care delivery system

INTERVENTIONS AND PRACTICES CONSIDERED

Assessment

1. Patient history and physical examination
2. BODE index:
    - Body mass index (BMI)
    - Degree of airflow obstruction
    - Dyspnea
    - Exercise capacity
3. Spirometry
4. Other investigations as indicated (alpha-1-antitrypsin deficiency, oximetry, chest X-ray, arterial blood gases, full pulmonary function tests, exercise testing, electrocardiogram, echocardiogram, sputum cultures, complete blood count)
5. Assessment of chronic obstructive pulmonary disease (COPD) severity
6. Screening for depression and anxiety

Management/Treatment

1. Smoking cessation
2. Influenza and pneumococcal vaccination
3. Patient education and self management
4. Oxygen therapy
5. Pulmonary rehabilitation
6. Alpha-l-antitrypsin augmentation therapy
7. Lung volume reduction surgery
8. Lung transplantation surgery
9. Pharmacotherapy
    - Short-acting bronchodilators (short-acting anticholinergics [SAAC] or short-acting beta 2-agonists [SABA])
    - Long-acting inhaled beta 2-agonists (LABA)
    - Long-acting inhaled anticholinergics (LAAC)
    - Combination inhaled bronchodilators
    - Inhaled glucocorticoids
    - Theophylline
10. Management of associated conditions (pulmonary hypertension, cor pulmonale, depression and anxiety, malnutrition, sleep disorders)
11. Referral to specialists
12. Pre-operative evaluation and management for patients needing surgery
13. Pre flight evaluation for patients planning air travel
14. Follow up monitoring

15. Palliative and end-of-life care

Management/Treatment of Acute Exacerbations

1. Assessment of need for emergency department/hospital admission
2. Short-acting bronchodilator and oxygen therapy
3. Clinical evaluation in the emergency department
4. Pharmacotherapy for acute exacerbations in the outpatient setting
    - Bronchodilator therapy (SAAC or SABA)
    - Antibiotics
    - Oral glucocorticoids

MAJOR OUTCOMES CONSIDERED

- Change in forced expiratory volume in one second (FEV1)
- Change in lung volume
- Degree of dyspnea
- Number and frequency of acute exacerbations
- Change in exercise endurance
- Disease modifier; reduction in progression rate
- Mortality
- Adverse effects from therapy (harm)
- Health-related quality of life (QOL)
- Healthcare utilization:
    - Number of hospital admissions for chronic obstructive pulmonary disease (COPD)
    - Length of hospitalization

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The Management of Chronic Obstructive Pulmonary Disease (COPD) Working Group developed researchable questions (see Appendix A of the original guideline document) and associated key terms after orientation to the scope of the guideline and to goals that had been identified by the Working Group. The questions specified (adapted from the Evidence-Based Medicine toolbox, Center for Evidence-Based Medicine, (http://www.cebm.net):

Population – Characteristics of the target patient population

Intervention – Exposure, diagnostic, or prognosis

Comparison – Intervention, exposure, or control used for comparison

Outcome – Outcomes of interest

Selection of Evidence

The evidence selection was designed to identify the best available evidence to address each key question and ensured maximum coverage of studies at the top of the hierarchy of study types. Published, peer-reviewed randomized clinical trials (RCTs), as well as meta-analyses and systematic reviews that include randomized controlled studies were considered to constitute the strongest level of evidence in support of guideline recommendations. This decision was based on the judgment that RCTs provide the clearest, scientifically sound basis for judging comparative efficacy. The Working Group made this decision recognizing the limitations of RCTs, particularly considerations of generalizability with respect to patient selection and treatment quality. When available, the search sought out critical appraisals already performed by others that described explicit criteria for deciding what evidence was selected and how it was determined to be valid. The sources that have already undergone rigorous critical appraisal include Cochrane Reviews, Best Evidence, Technology Assessment, and AHRQ systematic evidence reports.

In addition to Medline/PubMed, the following databases were searched: Database of Abstracts of Reviews of Effectiveness (DARE) and Cochrane Central Register of Controlled Trials. For Medline/PubMed searches, limits were set for language (English), and type of research (RCT, systematic reviews and meta-analysis).

As a result of the literature reviews, articles were identified for possible inclusion. These articles formed the basis for formulating the guideline recommendations. The following inclusion criteria were used for selecting randomized controlled trial studies:

- English language only
- Full articles only
- Age limited to adults greater than 18 years
- Randomized controlled trials or prospective studies
- Key outcomes cited

The Medical Subject Headings (MeSH) include: (Diseases; Respiratory Tract Diseases; Lung Diseases; Lung Diseases - Obstructive, Atelectasis, Bronchopulmonary Dysplasia; Asthma, Bronchitis, Pulmonary Emphysema). Selection of articles was then based on key therapies in COPD, study characteristics, and study design. In this search, "study characteristics" are those of prospective studies, cross-sectional studies, controlled clinical trials, randomized clinical trials (RCTs), systematic reviews and meta-analyses of RCTs.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Quality of Evidence

I	At least one properly done randomized controlled trial (RCT)
II-1	Well designed controlled trial without randomization
II-2	Well designed cohort or case-control analytic study
II-3	Multiple time series, dramatic results of uncontrolled experiment
III	Opinion of respected authorities, case reports, and expert committees

Overall Quality

Good	High grade evidence (I or II-1) directly linked to health outcome
Fair	High grade evidence (I or II-1) linked to intermediate outcome; or grade evidence (II-2 or II-3) directly linked to health outcome
Poor	Level III evidence or no linkage of evidence to health outcome

Net Effect of the Intervention

Substantial	More than a small relative impact on a frequent condition with a substantial burden of suffering or A large impact on an infrequent condition with a significant impact on the individual patient level.
Moderate	A small relative impact on a frequent condition with a substantial burden of suffering or A moderate impact on an infrequent condition with a significant impact on the individual patient level.
Small	A negligible relative impact on a frequent condition with a substantial burden of suffering or A small impact on an infrequent condition with a significant impact on the individual patient level.
Zero or Negative	Negative impact on patients or No relative impact on either a frequent condition with a substantial burden of suffering; or an infrequent condition with a significant impact on the individual patient level.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Preparation of Evidence Tables (Reports) and Evidence Rating

The results of the search were organized and evidence reports as well as copies of the original studies were provided to the Working Group for further analysis. Each reference was appraised for scientific merit, clinical relevance, and applicability to the populations served by the Federal healthcare system. Recommendations were based on consensus of expert opinions and clinical experience only when scientific evidence was unavailable.

A group of research analysts read and coded each article that met inclusion criteria. The articles have been assessed for methodological rigor and clinical importance.

The information was synthesized and reported in a brief summary of the critical appraisal of each article that included the following components:

- Description of patient population
- Interventions
- Comparisons
- Outcomes
- Summary of results
- Analysis of findings
- Evidence appraisal
- Clinical significance

Recommendation and Overall Quality Rating

Evidence-based practice involves integrating clinical expertise with the best available clinical evidence derived from systematic research. The Working Group received an orientation and tutorial on the evidence United States Preventive Service Task Force (USPSTF) 2001 rating process, reviewed the evidence and independently formulated Quality of Evidence ratings, a rating of Overall Quality, and a Strength of Recommendation (see "The Rating Scheme for the Strength of Evidence" field).

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The update of the Veterans Affairs/Department of Defense (VA/DoD) Clinical Practice Guideline for the Management of Chronic Obstructive Pulmonary Disease (COPD) was initiated in summer of 2005. The development process followed the steps described in "Guideline for Guidelines," an internal working document of the VA/DoD Evidence Based Practice Working Group, that requires an ongoing review of the work in progress. The Working Group of the VA/DoD was charged to update the evidence-based action recommendations whenever possible.

Guideline Development Process

The Offices of Quality and Performance and Patient Care Services, in collaboration with the network Clinical Managers, the Deputy Assistant Under Secretary for Health, and the Medical Center Command of the DoD identified clinical leaders to champion the guideline development process. During a preplanning conference call, the clinical leaders defined the scope of the guideline and identified a group of clinical experts from the VA and DoD that formed the Management of COPD Working Group. Working Group members included representatives of the following specialties: Pulmonology, Internal Medicine, Primary Care, Physiotherapy, Nursing, and Pharmacology.

As a first step, the Working Group defined a set of clinical questions within the area of the guideline. This ensured that the guideline development work outside the meeting focused on issues that practitioners considered important and produced criteria for the search and the protocol for systematic review and, where appropriate, meta-analysis.

The Working Group participated in an initial face-to-face meeting to reach consensus about the guideline algorithm and recommendations and to prepare a draft document. The draft continued to be revised by the Working Group at-large through numerous conference calls and individual contributions to the document. Following the initial effort, an editorial panel of the Working Group convened to further edit the draft document. Recommendations for the performance or exclusion of specific procedures or services were derived through a rigorous methodological approach that included the following:

- Determining appropriate criteria, such as effectiveness, efficacy, population benefit, or patient satisfaction
- Reviewing literature to determine the strength of the evidence in relation to these criteria
- Formulating the recommendations and grading the level of evidence supporting the recommendation

This Guideline is the product of many months of diligent effort and consensus building among knowledgeable individuals from the VA, DoD, academia, and guideline facilitators from the private sector. An experienced moderator facilitated the multidisciplinary Working Group.

The draft document was discussed in 2 face-to-face group meetings. The content and validity of each section was thoroughly reviewed through several conference calls. The final document is the product of those discussions and has been approved by all the members of the Working Group. The list of participants is included in Appendix E of the original guideline document.

Lack of Evidence—Consensus of Experts

Where existing literature was ambiguous or conflicting, or where scientific data was lacking on an issue. Recommendations were based on the clinical experience of the Working Group. These recommendations are indicated in the evidence tables are based on "Working Group Consensus."

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Strength of Recommendation

	Net Benefit of the Intervention			
Quality of Evidence	**Substantial**	**Moderate**	**Small**	**Zero or Negative**
Good	A	B	C	D
Fair	B	B	C	D
Poor	I	I	I	I

Evidence Rating System

A	A strong recommendation that the clinicians provide the intervention to eligible patients. *Good evidence was found that the intervention improves important health outcomes and concludes that benefits substantially outweigh harm.*
B	A recommendation that clinicians provide (the service) to eligible patients. *At least fair evidence was found that the intervention improves health outcomes and concludes that benefits outweigh harm.*
C	No recommendation for or against the routine provision of the intervention is made. *At least fair evidence was found that the intervention can improve health outcomes, but concludes that the balance of benefits and harms is too close to justify a general recommendation.*
D	Recommendation is made against routinely providing the intervention to asymptomatic patients. *At least fair evidence was found that the intervention is ineffective or that harms outweigh benefits.*
I	The conclusion is that the evidence is insufficient to recommend for or against routinely providing the intervention. *Evidence that the intervention is effective is lacking, or poor quality, or conflicting, and the balance of benefits and harms cannot be determined.*

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The draft document was reviewed by a diverse group of experts and by independent peer reviewers, whose input was also considered. The final document was submitted for review and approval by the Veterans Administration/Department of Defense (VA/DoD) Evidence-Based Practice Working Group.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The recommendations for the management of chronic obstructive pulmonary disease are organized into 3 major sections: Management of Chronic Obstructive Pulmonary Disease (COPD), Management of COPD Acute Exacerbations, and Pharmacotherapy. The quality of evidence **(QE)** grading (I-III); overall quality (**Good, Fair, Poor**); and final grade of recommendations **(R)** (A-D, I) are provided for specific statements. These grades, along with "net effect of the interventions" are defined at the end of the "Major Recommendations" field.

Note: A list of abbreviations is provided at the end of the "Major Recommendations" field.

Key Changes in the Guideline Update to Version 2.0

The revised guideline recommendations continue to support the Step-Care Therapy approach suggested first in the 1999 version of the Veterans Affairs/Department of Defense (VA/DoD) guideline for COPD; however, studies in recent years allowed the Working Group to make firmer recommendations in the following areas:

- The Step-Care Therapy approach is based on symptom scores
- Stronger evidence of the efficacy of each component of therapy
- Substantial evidence supporting the recommendation of long-acting bronchodilators as maintenance therapy
- Firm evidence supporting the recommendation for long-acting beta2-agonists (LABA) and inhaled glucocorticoids
- Accumulating strong evidence for the referral of patients with severe COPD to pulmonary rehabilitation

The format of the guideline has also been changed, combining several modules of the original guideline into one algorithm focusing on primary care and improving the guideline with a shorter version and more practical approach. Great effort was taken in this update to provide clear objectives and direct recommendations in a behavioral format. Establishing a set of desired treatment behaviors will hopefully

make implementation much easier. Elaboration of the recommendations and a review of the evidence are included in the Discussion section of each annotation.

Key Elements Addressed by this Guideline

1. Consider the diagnosis of COPD in all smokers and ex-smokers over the age of 45; cigarette smoking accounts for about 85 percent of the risk of developing COPD.
2. Smoking cessation is the single most effective way to reduce the risk of developing COPD and slow the rate of decline in lung function compared to that of non-smokers.
3. The diagnosis of COPD rests on the clinical history and on the requirement that spirometry demonstrates an airflow limitation that is not fully reversible.
4. Spirometry is the most reproducible, standardized, and objective way of measuring airflow limitation and is closely associated with prognosis.
5. Airflow limitation that is not fully reversible is defined as being present when the post-bronchodilator values for the ratio of forced expiratory volume in one second (FEV1) to forced vital capacity (FVC) (FEV1/FVC) is below 0.70.
6. Severity of COPD is based on the level of airflow limitation; tailored therapy for COPD is based on the severity of symptoms and functional limitation.
7. Breathlessness and functional limitation can be rated numerically with the simple Modified Medical Research Council (MMRC) dyspnea scale.
8. Step-Care for bronchodilators:
    - Inhaled bronchodilators provide symptom relief.
    - Long-acting bronchodilators provide sustained relief of symptoms in moderate to very severe COPD.
    - Combination therapy is useful in moderate and very severe COPD.
    - Adding inhaled glucocorticoids to optimize bronchodilator therapy reduces exacerbations in patients with both severe COPD (FEV1 <50 percent predicted) and frequent exacerbations (> one/year); long-term use of oral glucocorticoids is not recommended.

9. Pulmonary rehabilitation reduces dyspnea, anxiety, and depression; improves exercise capacity and quality of life (QOL); and may reduce hospitalizations
    - Exercise alone or as part of a comprehensive rehabilitation program improves symptoms, self-confidence, endurance, and QOL.

10. Long-term oxygen for more than 15 hours/day prolongs life in hypoxemic patients with partial pressure of oxygen in arterial blood (PaO_2) of 55 mm Hg or less.
11. Diagnostic sleep tests should be considered if patients with COPD have pulmonary hypertension, hypercapnia, and daytime somnolence or witnessed apneas.
12. End-of-life care in patients with end-stage COPD may be considered.

Module A : Management of COPD

Management of Outpatient COPD Algorithm

1. **Definition and Case Finding of COPD**

    Action Statement

The diagnosis of COPD should be suspected in any patient who has a history of tobacco use (smoking) and any of the following [**C**]:

- Chronic cough, or
- Chronic sputum production, or
- Dyspnea on exertion or rest

The diagnosis of COPD must be confirmed by spirometry. [**I**]

Recommendations

1. Persons with a history of smoking and the presence of cough or chronic sputum production or dyspnea should be assessed for COPD with spirometry. [**C**]

	Evidence	Source	QE	Overall Quality	R
1	Twenty-seven percent of patients over 35 years old were current or ex-smokers who had a chronic cough and a reduced FEV1.	Van Schayck et al., 2002	II-2	Fair	C
2	Significant proportion of patients with chronic bronchitis will develop airflow limitation.	Jonsson et al.,1998	II-2	Fair	C

QE = Quality of Evidence; R = Strength of Recommendation (See Appendix A in the original guideline document)

2. Assessment, Testing, and Diagnosis

2.1 Clinical Assessment: History and Physical Examination

Action Statement

All patients with known or suspected COPD should have a focused history and physical examination to assess for the presence of airflow limitation. [**I**]

Recommendations

1. The following core elements of the medical history should be evaluated in patients with suspected or proven COPD [**I**]:
    a. *Shortness of breath* — Patients should quantify their level of dyspnea (resting vs. exertional). Early in the disease course, patients often complain of exertional dyspnea. As the disease progresses, exercise tolerance worsens and patients may develop resting dyspnea.

b. *Cough* — Duration and character of the cough should be quantified. The presence of a productive cough is a second clinical hallmark of COPD. This cough is typically initially worse in the morning, but can be present throughout the day. An isolated nocturnal cough is typically not characteristic of COPD. Chronic bronchitis is defined by the presence of a persistent cough for at least 3 months for 2 or more consecutive years.
c. *Sputum production* - Volume (amount) and character (color, thickness) of sputum production should be qualified. Sputum production is required for a diagnosis of chronic bronchitis.
d. *Risk factor assessment* — Tobacco use, particularly cigarette smoking, is the primary risk factor for developing COPD. Use should be quantified in pack-years (number of packs per day x number of years = pack-years). A 10-pack year history of smoking is considered to be the threshold for development of COPD. There is no comparable standard for pipes or cigars that may also produce COPD. Environmental pollutant exposure and occupational exposure to vapors, fumes, or irritants are important secondary risk factors.
e. *Other important elements in the initial evaluation of COPD*:
    - Prior medical history of asthma, allergies, or recurrent respiratory illnesses (particularly in childhood)
    - Family history of COPD
    - Self-reported history of prior COPD exacerbations and/or hospitalizations
    - Presence of comorbid conditions, in particular coronary artery disease, congestive heart failure, depression, and anxiety

2. The following core elements of the physical examination should be evaluated in patients with suspected or proven COPD [**I**]:
    a. *Vital signs* — For patients with COPD, an assessment of pulse oximetry and body mass index (BMI = kg/m^2) should be included with the vital signs.
    b. *Inspection* — Clinical observation should be performed to assess for the following elements:
        - Chest wall morphology (e.g., 'barrel-chest'); use of accessory muscles (e.g., 'suprasternal retractions'); pursed-lip breathing (surrogates that suggest airflow limitation); and tracheal tug (sign of hyperinflation)
        - Forced Expiratory Time — Patients should be asked to completely empty their lungs following a maximal inspiratory effort
        - Central cyanosis (a surrogate for oxygen saturation); oxygen desaturation may be present in the absence of cyanosis; cyanosis is indicative of severe desaturation
        - Miscellaneous signs — Jugular venous distension suggests elevated right heart pressures; bilateral peripheral edema may suggest cor pulmonale.
    c. *Palpation/Percussion* — These elements are often unhelpful in patients with COPD, but may be helpful in diagnosing pulmonary hyperinflation.

d. *Auscultation* — The following elements should be noted on the cardiopulmonary examination:
    - Breath sounds are often diminished or distant in patients with COPD.
    - A widened split second heart sound is suggestive of cor pulmonale.

2.2 Spirometry and Reversibility for Diagnosis

Action Statement

Spirometry should be obtained in all stable patients suspected of or having a diagnosis of COPD. [**B**]

Recommendations

1. Spirometry should be performed and documented in the medical record. [**B**]
2. A diagnosis of expiratory airflow limitation can be made if the post-bronchodilator FEV1/FVC or FEV1/vital capacity (VC) ratio is 0.70 or less. Where possible, value should be compared to age-related normal values to avoid over diagnosis of COPD in the elderly. [**I**]
3. Reversibility should not be used to predict response to treatment or to distinguish between COPD and asthma. [**B**]
4. Spirometry should be repeated if there is a clinically significant unexplained change in respiratory symptoms. [**I**]
5. All patients presenting with airflow limitation at a relative early age (of the fourth to fifth decade) or with a family history of COPD should be tested for alpha-1-antitrypsin deficiency. [**I**]
6. Oximetry should be considered in patients with COPD and should be performed in all patients with severe or very severe COPD (FEV1 <50 percent predicted) to determine the degree of hypoxemia and the potential need for long-term oxygen therapy at rest and/or during exercise. [**C**]

	Evidence	**Source**	**QE**	**Overall Quality**	**R**
1	Perform spirometry (pre- and post-bronchodilator) in all stable patients suspected or having a diagnosis of COPD.	Celli & MacNee, 2004 Global Obstructive Lung Disease (GOLD), 2005 National Collaborating Centre for Chronic Conditions, 2004	III	Poor	B
2	Spirometry is most useful	Wilt et al., 2005	I	Good	A

	Evidence	Source	QE	Overall Quality	R
	for the diagnosis of patients with severe to very severe COPD.				
3	A diagnosis of expiratory airflow limitation can be made if the post-bronchodilator FEV1/FVC or FEV1/VC ratio is <0.70.	Celli & MacNee, 2004 GOLD, 2005	III	Poor	I
4	Reversibility does not predict response to treatment or distinguish between COPD and asthma.	National Collaborating Centre for Chronic Conditions, 2004	II-3	Fair	B

QE = Quality of Evidence; R = Strength of Recommendation (See Appendix A in the original guideline document)

2.3 Assessing Severity of the Disease

Action Statement

COPD severity should be assessed on the basis of percentage of predicted FEV1 or degree of dyspnea related to activities. [**I**]

Recommendations

1. The FEV1 should be used to stratify disease severity by airflow limitation. [**B**]
2. The MMRC Dyspnea Scale should be used to grade severity of breathlessness according to the level of exertion required to elicit it and help determine treatment. [**C**]

   Spirometric classification of disease stages and severity is described in Table 1 below. The severity of COPD that is based on self-reported symptoms is described in Table 2 below using the Dyspnea Scale developed by the Medical Research Council.

Table 1. Severity of COPD Based on Spirometry (*adopted from Celli & MacNee, 2004*)

Stage	Severity	Post-bronchodilator FEV1/FVC	FEV1 % predicted
0	At-Risk*	>0.7	$\geq$80
1	Mild	$\leq$0.7	$\geq$80

Stage	Severity	Post-bronchodilator FEV1/FVC	FEV1 % predicted
2	Moderate	≤0.7	50–79.9
3	Severe	≤0.7	30–49.9
4	Very Severe	≤0.7	<30
* Patients who smoke or are exposed to pollutants; and have cough, sputum or dyspnea; or have family history of respiratory disease. (There is insufficient evidence to support this category.)			

Table 2. Severity of COPD Based on Dyspnea*

Severity	Score	Degree of Breathlessness Related to Activities
None	0	Not troubled with breathlessness except with **strenuous exercise**
Mild	1	Troubled by shortness of breath when hurrying or walking up a **slight hill**
Moderate	2	Walks slower than people of the same age due to breathlessness or has to stop for breath when walking at own pace **on the level**
Severe	3	**Stops** for breath after walking approximately 100 meters or after **a few minutes** on the level
Very Severe	4	Too breathless to **leave the house** or breathless when **dressing or undressing**
* MMRC Dyspnea Scale (Bestall et al., 1999)		

	Evidence	Source	QE	Overall Quality	Net Effect	R
1	FEV1 indicates severity of the disease.	Anthonisen, Wright, & Hodgkin, 1986 Burge et al., 2003 Dewan et al., 2000 Ferrer et al., 1997 Friedman et al., 1999	II-2	Fair	Substantial	B

	Evidence	Source	QE	Overall Quality	Net Effect	R
2	Dyspnea is a better predictor of mortality than FEV1.	Nishimura et al., 2002	II-2	Fair	Substantial	C
3	The BMI, Airflow Obstruction, Dyspnea, Exercise Performance (BODE) Index is a better predictor for the risk of death from COPD.	Celli et al., 2004	II-2	Fair	Moderate	B

QE = Quality of Evidence; R = Strength of Recommendation (See Appendix A in the original guideline document)

2.4 Diagnostic Workup

Action Statement

Other investigations, in addition to spirometry, may be necessary as clinically indicated. [**I**]

Recommendations

1. A diagnosis of COPD requires objective evidence of airflow obstruction via pre- and post-bronchodilator spirometry. [**B**]
2. A chest X-ray should be considered to rule out other diagnoses and for later use as a baseline. A chest X-ray is not sensitive for the diagnosis of COPD. [**C**]
3. Other investigations may be necessary as clinically indicated [**I**]:
    a. *Computed Tomography (CT)* — Can exclude other diseases and define bullae and is essential to identify patients eligible for lung volume reduction surgery
    b. *Oximetry* — Should be considered in patients with COPD and should be performed in all patients with severe or very severe COPD (FEV1 <50 percent predicted) to determine the degree of hypoxemia and the potential need for long-term oxygen therapy at rest and/or during exercise. Nocturnal pulse oximetry should be performed in patients considered solely for nocturnal oxygen supplementation.
    c. *Alpha-1-antitrypsin (AAT)* — AAT deficiency accounts for less than one percent of COPD. It should be suspected if there is early onset of COPD, little or no history of smoking, a family history of COPD, or a predominance of basilar emphysema. If AAT deficiency is suspected, obtain a serum AAT level.
    d. *Arterial blood gases* — Arterial blood gases should be done in patients with very severe COPD (FEV1 <30 percent predicted); signs of right heart failure (cor pulmonale); polycythemia (hematocrit >55 percent); or respiratory failure. Blood gases

are an alternative to pulse oximetry in patients being considered for oxygen (O_2) supplementation. Pulse oximetry can determine arterial oxygen saturation, but pulse oximetry does not yield PCO_2.

e. *Full pulmonary function tests* — Lung volumes, carbon monoxide diffusing capacity and flow-volume loops are not required for routine assessment but can provide additional information useful for resolving diagnostic uncertainty and/or assessing surgical risk. A reduced carbon monoxide diffusion capacity may suggest the presence of emphysema.
f. *Exercise testing* — Exercise testing may be of value in patients with a disproportionate degree of dyspnea for their FEV1. Exercise testing can quantify impairment and/or disability and help to select patients able to safely undergo lung resection.
g. *Electrocardiogram (ECG)* — To assess cardiac status if pulmonary or nonpulmonary heart disease is suspected or present.
h. *Echocardiogram* — To assess right and left cardiac status if cardiac dysfunction or disease is suspected or present.
i. *Sputum cultures* — Consider in patients with persistently purulent sputum or during recurrent infectious exacerbations.
j. *Complete blood count* — Should be done if anemia or polycythemia is suspected.

2.5 Referral to Pulmonary Consultant

Action Statement

Patients with severe COPD or comorbidity that requires complicated management should be referred to a pulmonary subspecialist. [**I**]

Recommendations

1. Patients with COPD should be referred for consultative opinion if they request it, if there is diagnostic uncertainty, if the disease is very severe or complicated, or if the primary care provider chooses so. [**I**]

3. Prevention Risk Reduction

3.1 Patient Education

Recommendations

1. Patient should be educated about the disease, cause, therapy, and complications of COPD. [**I**]

3.2 Smoking Cessation

Action Statement

All patients must be screened for tobacco use and encouraged to stop smoking at every visit, as smoking cessation is the only known intervention to reduce the decline in FEV1. [**A**]

Recommendations

1. All patients should be counseled not to smoke and to avoid secondhand smoke. [**A**]
2. All smokers must be told that they need to quit smoking. [**A**]
3. All smokers should be assessed for willingness to quit. [**C**]
4. All smokers should be counseled on smoking cessation and be considered for medications that assist in smoking cessation. [**A**]

See the original guideline document for 5 suggested strategies to promote smoking cessation (Table 3) and 5 motivational interventions to promote smoking cessation (Table 4).

	Evidence	Source	QE	Overall Quality	R
1	Passive smoke exposure increases cough and sputum production.	Leuenberger et al., 1994	I	Good	A
2	Smoking cessation decreases the loss of lung function.	Anthonisen et al., 1994	I	Good	A
3	Smoking cessation decreases mortality.	Anthonisen et al., 2005	I	Good	A

QE = Quality of Evidence; R = Strength of Recommendation (See Appendix A in the original guideline document)

3.3 Vaccination

Action Statement

Provide an annual influenza vaccine to individuals with COPD. [**A**]

Provide a pneumococcal polysaccharide vaccine to individuals with COPD. [**B**]

Recommendations

1. An annual influenza vaccination is recommended for individuals with COPD unless contraindicated due to severe anaphylactic hypersensitivity to egg protein. Only inactivated influenza vaccines should be used. The optimal time to receive influenza vaccine is October - November. [**A**]
2. Although insufficient data exist for use of pneumococcal vaccination in individuals with COPD, data from elderly populations with or without chronic disease provides supportive evidence for its use. [**A**]

3. Pneumococcal vaccines are routinely given as a one-time dose (administer if previous vaccination history is unknown). One-time revaccinations are recommended 5 years later for people at the highest risk for fatal pneumococcal infection and for people older than 65 years if the first dose was given prior to the age of 65 and more than 5 years have elapsed since the previous dose. [**I**]

	Evidence	Source	QE	Overall Quality	R
1	In the general elderly population, influenza vaccination reduced hospitalization for pneumonia and influenza and all-cause mortality.	Jefferson et al., 2005 Vu et al., 2002	I	Good	A
2	Influenza vaccination decreased COPD exacerbations.	Poole et al., 2006	I	Good	A
3	Influenza vaccination reduced the incidence of outpatient influenza-related acute respiratory illness events, but not influenza-related events leading to hospitalization.	Wongsurakiat et al., 2004	I	Good	A
4	In elderly patients with chronic lung disease, influenza vaccine reduced hospitalizations for pneumonia and influenza and for death.	Nichol, Baken, & Nelson, 1999	II-2	Good	B
5	In the general elderly population, pneumococcal vaccine reduces the risk of bacteremia/invasive pneumococcal disease.	Conaty et al., 2004 Cornu et al., 2001 Jackson et al., 2003	I	Good	A
6	In the general elderly population, pneumococcal vaccine does not appear to reduce the risk of all-cause pneumonias.	Jackson et al., 2003 Moore, Wiffen, & Lipsky, 2000 Watson, Wilson & Waugh, 2002	I	Fair	C
7	Pneumococcal vaccine reduces the risk of all-	Hedlund et al., 2003	I	Fair	C

	Evidence	Source	QE	Overall Quality	R
	cause pneumonias and risk of death due to pneumonia.	Nichol et al., 1999 Vila-Corcoles et al., 2006	I II-b		
8	PPV decreases the rate of pneumonia and mortality due to pneumonia in COPD.	Alfageme et al., 2006	I	Good	A

QE = Quality of Evidence; R = Strength of Recommendation (See Appendix A in the original guideline document)

4. Therapy Intervention for COPD

4.1 Pharmacotherapy for COPD

Key Points for Step-up Therapy

Pharmacotherapy for patients with COPD is based on a step-up approach:

1. Therapy to address symptoms should make use of non-pharmacologic intervention to improve outcomes (i.e., smoking cessation, education, rehabilitation, and pulmonary rehabilitation).
2. Pharmacotherapy should balance overall efficacy which includes acceptance and adherence against risks for adverse effects (toxicity).
3. Patient symptomatic responses such as dyspnea, as well as a reduction in exacerbations, should be the primary basis for determining response to therapy.
4. Continue ongoing evaluation of the patient's response to therapy and progression of disease.
5. As COPD progresses, additional pharmacotherapy is usually needed.
6. Patient's preference should be considered to improve acceptance and adherence to therapy.
7. Patients with severe airflow limitation (FEV1 <50 percent predicted) and minimal symptoms should be considered for a trial of pharmacologic therapy.
8. COPD severity based on symptoms and FEV1 should always be documented initially and reassessed periodically based primarily on symptomatic progression of COPD.
9. The MMRC scale of dyspnea, in addition to clinical assessment, is indicated to grade symptom severity.
10. Treatment is predominantly based on symptoms and a suggested stepped-up approach is recommended (see Table 3 below).

Table 3: Step-Care Pharmacotherapy in COPD (See also Figure 2 in the original guideline document)

Step	Symptoms[1]	Maintenance Therapy[2]	Rescue Therapy	Other Interventions
A	Asymptomatic	No medication indicated	--	Smoking cessation; influenza, and other vaccinations
B	Symptoms less than daily	No scheduled medication indicated	SABA[6]	Smoking cessation; influenza, and other vaccinations
C	Symptoms not controlled with rescue therapy **or** daily symptoms	Scheduled SAAC **or** Combination SABA + SAAC[3]	SABA[6]	Smoking cessation; influenza, and other vaccinations
D	Symptoms not controlled[2]	Combination SAAC + LABA **or** LAAC[4]	SABA[6]	Smoking cessation; influenza, and other vaccinations **Consider Pulmonary Rehabilitation**[7]
E	Symptoms not controlled[2]	Combination LABA + LAAC[4]	SABA[6]	Smoking cessation; influenza, and other vaccinations **Refer to Pulmonary Rehabilitation**[7]
F	Exacerbations of more than one per year and severe disease (FEV1 <50%)	Consider adding an inhaled glucocorticoid[5]	SABA[6]	Smoking cessation; influenza, and other vaccinations **Refer to Pulmonary Rehabilitation**[7]

11. **Spirometry** is essential to confirm the presence of airflow obstruction (low FEV1 and FEV1/VC ratio). Base therapy on symptoms, but consider alternate diagnoses (heart disease, pulmonary emboli, etc.) if out of proportion to spirometry.
12. Use the lowest level of therapy that satisfactorily relieves symptoms and maximizes activity level. Assure compliance and proper use of medications before escalating therapy. It is unusual for patients with COPD with **FEV1 above 70%** to require therapy beyond short-acting bronchodilators; if these patients do not improve

Step	Symptoms[1]	Maintenance Therapy[2]	Rescue Therapy	Other Interventions
they should be considered for alternative diagnoses. 13. Consider use of **inhaler** containing both a short-acting beta 2-agonist and an anticholinergic. Nighttime symptoms are frequently better controlled with a long-acting inhaled beta 2-agonist. 14. Consider adding a **theophylline trial** (slow release theophylline adjusted to the level of 5 to 12 micrograms/ml) with caution due to adverse effects. Nighttime respiratory symptoms are frequently controlled, but theophylline may lead to insomnia. Discontinue if a benefit is not evident within several weeks. 15. Consider high dose **inhaled glucocorticoids** in patients with severe COPD (FEV1 <50 % predicted) and at least one exacerbation in the prior year. A combination of a high dose inhaled glucocorticoid and a long-acting beta 2-agonist may help provide long-term maintenance for symptomatic COPD and improve quality of life (QOL). The use of oral glucocorticoids for maintenance therapy is discouraged. 16. Short-acting inhaled beta 2-agonists (less than12 puffs/day) may continue to be used as needed. Inhaled long-acting beta 2-agonists should not be used as rescue therapy. 17. **Pulmonary rehabilitation** should be offered to patients who, despite optimal medical therapy, have reduced exercise tolerance and/or dyspnea limiting exercise.				

See Table 7 in the original guideline document for effects of commonly used medications on clinical outcomes, along with strength of recommendation ratings.

4.2 Oxygen Therapy

Action Statement

Patients with COPD should be periodically evaluated for the need of supplemental oxygen. Supplemental oxygen for those exhibiting signs of tissue hypoxia may increase survival of patients with severe COPD. Oxygen may also be used for exertional hypoxemia or nocturnal hypoxemia.

Recommendations

1. Oximetry should be considered in patients with COPD and should be performed in all patients with severe or very severe COPD (FEV1 <50 percent predicted). [**I**]
2. Evaluation of nocturnal desaturation should be considered in patients with severe or very severe COPD (FEV1 <50 percent predicted) who exhibit unexplained findings indicating nocturnal hypoxemia (e.g., polycythemia, pulmonary hypertension, and nocturnal restlessness). [**I**]
3. Oxygen therapy should be initiated in patients who have hypoxemia ($PaO_2 \leq 55$ mm Hg and/or arterial blood oxygen saturation (SaO_2) ≤ 88 percent). [**A**]
4. Oxygen therapy should be initiated in patients who have hypoxemia (PaO_2 of 56 to 59 mm Hg or SaO_2 <89 percent) and signs of tissue hypoxia such as hematocrit above 55, pulmonary hypertension, or cor pulmonale. [**A**]

5. Oxygen therapy should be provided during exercise in stable patients with COPD with exertional hypoxemia ($SaO_2 \leq 88$ percent). [**B**]
6. Oxygen therapy should be considered for nocturnal hypoxemia ($SaO_2 < 88$ percent). [**I**]
7. Patients who started to receive oxygen therapy while unstable or on suboptimal medical therapy should be reevaluated within one to 3 months for need of long-term oxygen therapy (LTOT). If repeated evaluation indicates a patient no longer qualifies for oxygen, cessation of oxygen should be considered. [**B**]
8. Patients who continue to receive LTOT should be reevaluated at least annually for continued need of LTOT. [**I**]
9. Patients prescribed oxygen should be cautioned about the potentially extreme fire hazard of smoking or lighting cigarettes in the presence of oxygen. [**I**]

	Evidence	Source	QE	Overall Quality	R
1	Patients who have $PaO_2 \leq 55$mm Hg and/or $SaO_2 \leq 88$ percent will have mortality benefit with LTOT.	Cranston et al., 2005 "Continuous or nocturnal," 1980	I	Good	A
2	Oxygen administration slows progression of pulmonary hypertension in hypoxic patients with COPD.	"Long term domiciliary," 1981 "Continuous or nocturnal," 1980 Weitzenblum et al., 1985	I	Good	A
3	Patients with mild to moderate hypoxemia without signs of tissue hypoxia did not demonstrate a survival benefit after 3 years of LTOT.	Gorecka et al., 1997 Cranston et al., 2005	I	Good	D
4	Oxygen supplementation during exercise improves dyspnea, exercise tolerance, and performance.	Bradley & O'Neill, 2005 Eaton et al., 2002 Fujimoto et al., 2002 Garrod, Paul, & Wedzicha, 2000 McDonald et al., 1995	I	Good	A

	Evidence	Source	QE	Overall Quality	R
		Rooyackers et al., 1997 Stein, Bradley & Miller, 1982			
5	Nocturnal oxygen therapy improves pulmonary hypertension.	Fletcher et al., 1992	I	Good	A
6	Nocturnal oxygen therapy does *not* improve survival.	Chaouat et al., 1999	I	Good	A

QE = Quality of Evidence; R = Strength of Recommendation (See Appendix A in the original guideline document)

4.3 Pulmonary Rehabilitation

Action Statement

Pulmonary rehabilitation should be offered to all patients with COPD, who, despite optimal medical therapy, have reduced exercise tolerance and/or dyspnea limiting exercise. [**A**]

All patients with COPD with exertional symptoms should be offered a structured program with exercise training to reduce dyspnea and improve exercise tolerance and health-related QOL. [**A**]

Pulmonary rehabilitation programs with educational components and self-management training reduce healthcare use. [**B**]

Recommendations

Selection of Patients

1. Pulmonary rehabilitation should be considered for patients with COPD who have dyspnea, reduced exercise tolerance, a restriction in activities, or impaired health status. [**A**]
2. Pulmonary rehabilitation should be offered to all patients who consider themselves disabled by COPD (Level 3 and above on the dyspnea scale). [**B**]
3. Pulmonary rehabilitation is recommended for patients with reduced exercise tolerance and restricted activities because of dyspnea. [**A**]

Exercise Training

4. The exercise program should be supervised and should provide cardiovascular reconditioning with endurance and muscle strength training. [**A**]
5. The initial exercise program should be of sufficient length, duration, and frequency (see Appendix B: Structured Exercise Training Program in the original guideline document). [**B**]
6. Endurance training should be performed to improve physical endurance. [**A**]
7. Lower limb strength training should be performed to improve exercise tolerance (walking, cycling); upper extremity training improves arm strength. [**B**]
8. In order to maintain benefits, subsequent exercise training is needed. [**B**]
9. As studies show conflicting results, respiratory muscle training is not recommended to be part of a rehabilitation exercise program. [**B**]

Education and Self-Management

10. Patients with COPD with a prior hospitalization should be referred for pulmonary rehabilitation. [**A**]
11. Educational components and self-management programs should be included in rehabilitation programs, as it can reduce COPD exacerbations, hospital admission, and length of stay. [**B**]
12. Self-management programs should include the following [**B**]:
    a. Skills training to optimally control the disease
    b. Education about medications and devices and how to use them properly
    c. Instruction on how to deal with exacerbations
    d. Other aspects of coping with the disease

13. The benefit of education, psychosocial support, and nutritional therapy as a single intervention, without exercise, are less well-documented. [**I**]

	Evidence	Source	QE	Overall Quality	Net Effect	R
1	Significant improvement in dyspnea and COPD QOL (measured by the Chronic Obstructive Pulmonary Disease [CRDQ]).	Pulmonary rehabilitation: joint American College of Chest Physicians (ACCP) /American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR), 1997	I	Good	Substantial	A

	Evidence	Source	QE	Overall Quality	Net Effect	R
		Lacasse et al., 2002				
2	Significant improvement in dyspnea and exercise capacity for patients with an FEV1 above 35 percent for long-and short-term programs. Patients with FEV1 below 35 percent required at least 6 months of program.	Salman et al., 2003	I	Good	Substantial	A
3	Rehabilitation improved dyspnea, QOL, and exercise capacity.	Kupferberg et al., 2005 Ries et al., 2005	II-2	Fair	Substantial	B
4	Addition of supervised exercise to a dyspnea self-management program that included unsupervised home exercise (walking) led to greater improvement in dyspnea, QOL and exercise capacity	Carrieri-Kohlman et al., 2005	I	Good	Substantial	A
5	Home-based rehabilitation improved exertional dyspnea (Borg), QOL (CRDQ) and exercise capacity.	Oh, 2003	I	Fair	Moderate	B
Exercise						
6	Rehabilitation improves exercise endurance and maximal exercise capacity.	Pulmonary rehabilitation: joint ACCP/AACVPR, 1997 Lacasse et al., 2002	I	Good	Substantial	A
7	Rehabilitation improves peripheral muscle strength.	Troosters et al., 2005	I	Good	Moderate	B

	Evidence	Source	QE	Overall Quality	Net Effect	R
8	Improvements in exercise tolerance are maintained for 6 months to a year.	Bestall et al., 2003	I	Fair	Small	C
9	Respiratory muscle training can improve strength of these muscles, but this does not lead to increased exercise tolerance or better QOL.	Lotters et al., 2002 Smith et al., 1992	I	Good	Zero	D
Education and Self-Management						
10	Pulmonary rehabilitation program with educational components and structured treatment recommendations for COPD exacerbation reduce healthcare use.	Bourbeau et al., 2003 Gadoury et al., 2005 Gallefoss & Bakke, 2000 Griffiths et al., 2000 Guell et al., 2000 Troosters et al., 2005	I	Fair	Moderate	B
11	Self-management programs (that include education about the medications and how to use them, guide behavior change, and provide emotional support) reduce COPD exacerbations, and hospital admissions, and length of stay.	Bourbeau et al., 2003 Gallefoss & Bakke, 2000 Guell et al., 2000 Monninkhof et al., 2003 Troosters et al., 2005	I	Fair	Moderate	B

QE = Quality of Evidence; R = Strength of Recommendation (See Appendix A in the original guideline document)

4.4 Mucolytics, Antioxidants and Antitussives

Action Statement

The use of mucolytics, antioxidants, or antitussive medications has little evidence of any effect on lung function. [**D**]

Recommendations

1. N-acetylcysteine (NAC) is not recommended for patients with COPD for the purpose of cough suppression. [**D**]
2. N-acetylcysteine (NAC) 600 mg by mouth every day may be considered to decrease the number of exacerbations in selected patients with COPD with primarily chronic bronchitis who are not on inhaled glucocorticoids. [**B**]
3. Antioxidants, such as alpha-tocopherol (contained in vitamin E preparations) or beta-carotene, should not be administered to patients with COPD, as they have no significant effect on phlegm, cough, or dyspnea. [**D**]
4. Antitussives are not indicated in stable COPD. [**I**]

	Evidence	Source	QE	Overall Quality	R
1	There is *no* effect of NAC on rate of decline in FEV1 or exacerbations in COPD.	Decramer et al., 2005	I	Good	D
2	Exacerbations may be decreased with NAC 600 mg by mouth every day or other mucolytics in patients with chronic bronchitis not on inhaled glucocorticoids.	Decramer et al., 2005 Grandjean et al., 2000 Poole & Black, 2006 Stey et al., 2000	I	Good	B
3	The antioxidants alpha-tocopherol and beta-carotene are *not* effective in COPD.	"The alpha-tocopherol," 1994 Rautalahti et al., 1997	I	Good	D
4	Antitussives *not* effective in COPD.	National Collaborating Centre for Chronic Conditions, 2004	III	Poor	I

QE = Quality of Evidence; R = Strength of Recommendation (See Appendix A in the original guideline document)

4.5 Alpha-l-Antitrypsin Augmentation Therapy

Action Statement

Patients with COPD due to confirmed or suspected AAT deficiency should be referred to a pulmonary subspecialist. [**C**]

AAT augmentation therapy should be considered in patients with severe hereditary AAT deficiency and established emphysema. [**C**]

Recommendations

1. Patients with COPD due to AAT deficiency should be provided the usual COPD therapy—smoking cessation, preventive vaccinations, bronchodilators, supplemental oxygen if indicated, and pulmonary rehabilitation. [**I**]
2. Patients with severe AAT deficiency who have stopped smoking and with moderate to severe COPD (FEV1 30 to 60 percent predicted) should be considered for AAT augmentation therapy. Furthermore, benefits are not clear for those with FEV1 either below 30 percent or above 60 percent predicted. [**C**]
3. Augmentation therapy is not indicated for patients without emphysema. [**D**]

	Evidence	Source	QE	Overall Quality	R
1	AAT augmentation therapy may slow the decline in lung function, reduce infection rates, and enhance survival in patients with emphysema and severe AAT deficiency.	"Survival," 1998 American Thoracic Society/European Respiratory Society (ATS/ERS), 2003 Dirksen et al., 1999 Stoller & Abboussouan, 2005	II-2	Fair	C
2	AAT therapy may be most effective in patients with FEV1 30 to 60 percent predicted and is probably ineffective in patients outside that range.	"Survival," 1998	II-2	Good	C

QE = Quality of Evidence; R = Strength of Recommendation (See Appendix A in the original guideline document)

4.6 Lung Volume Reduction Surgery

Action Statement

Consider lung volume reduction surgery (LVRS) in carefully selected patients with very severe COPD who comply with selection criteria used in studies demonstrating benefit from this intervention. [**A**]

Recommendations

1. Referral for LVRS may be considered for patients with very severe COPD if they meet the following criteria [**A**]:
    a. High-resolution CT confirming bilateral emphysema
    b. Total lung capacity before rehabilitation and after treatment with bronchodilators is greater than 100 percent predicted and residual volume is greater than 150 percent predicted
    c. Post-bronchodilator FEV1 is less than 45 percent predicted
    d. $PaCO_2$ less than 60 mm Hg, and PaO_2 greater than 45 mm Hg
    e. Patient has completed a pulmonary rehabilitation program.

2. LVRS should not be considered in patients whose FEV1 is less than 20 percent predicted and who either have homogenous emphysema or carbon monoxide diffusing capacity that is less than 20 percent or have non-upper lobe emphysema and high baseline exercise capacity. [**D**]
3. LVRS should only be performed in medical centers with appropriately trained surgeons and availability of necessary equipment. [**I**]

	Evidence	Source	QE	Overall Quality	R
1	LVRS yielded a survival advantage only for patients with upper lobe emphysema and low baseline exercise capacity.	Fishman et al., 2003	I	Good	B
2	LVRS demonstrated increased mortality and no functional improvement for patients with non-upper lobe emphysema.	Berger et al., 2005 Fishman et al., 2003	I	Good	D
3	LVRS improved exercise capacity and QOL after 2 years among patients with upper lobe emphysema.	Fishman et al., 2003 Naunheim et al., 2006 Tiong et al., 2006	I	Good	A

	Evidence	Source	QE	Overall Quality	R
4	LVRS increases mortality compared to optimum medical therapy in patients with COPD with FEV1 <20 percent and homogenous emphysema in chest CT scan or diffusing capacity <20 percent.	Fishman et al., 2003	I	Good	D

QE = Quality of Evidence; R = Strength of Recommendation (See Appendix A in the original guideline document)

4.7 Lung Transplantation Surgery

Action Statement

For patients with severe symptoms, despite maximal medical therapy, lung volume reduction surgery and transplantation may be an option. [**C**]

Recommendations

1. Lung transplantation may be considered in selected patients with advanced COPD. The choice of single lung transplantation (SLT) or bilateral lung transplantation (BLT) for COPD remains controversial. [**C**]

<u>COPD Disease-Specific Guidelines for Candidate Selection for Lung Transplantation</u>

Guidelines for Referral

- BODE index exceeding 5 (Stands for BMI, Obstructive pulmonary function, dyspnea by MMRC and Exercise by 6-minute walk distance)

Guidelines for Transplantation

- Patients with a BODE index of 7 to 10 or at least 1 of the following:
    - History of hospitalization for exacerbation associated with acute hypercapnia (PCO_2 exceeding 50 mm Hg).
    - Pulmonary hypertension or cor pulmonale, or both, despite oxygen therapy.
    - FEV1 of less than 20 percent and either DLCO of less than 20 percent or homogenous distribution of emphysema.

	Evidence	Source	QE	Overall Quality	R

	Evidence	Source	QE	Overall Quality	R
1	Lung transplantation results in highly selected patients improved: pulmonary function, exercise capacity.	Arcasoy & Kotloff, 1999 Bando et al., 1995 Mal et al., 1994	III	Fair	C
2	Lung transplantation results in highly selected patients improved quality of life	Orens et al., 2006	III	Good	C
3	Lung transplantation results in highly selected patients improved survival.	Hosenpud et al., 1998	III	Poor	I

QE = Quality of Evidence; R = Strength of Recommendation (See Appendix A in the original guideline document)

5. Management of Associated Conditions

5.1 Pulmonary Hypertension and Cor Pulmonale in COPD

Action Statement

Patients with pulmonary hypertension and/or cor pulmonale should be referred to a specialist for the management of COPD and be provided long-term oxygen, if needed, and optimized. [**A**]

Recommendations

1. Patients with diagnosed or suspected cor pulmonale should be referred to a pulmonary subspecialist. [**C**]
2. Patients with pulmonary hypertension and/or cor pulmonale should be assessed for hypoxemia and provided long-term oxygen, if needed. [**A**]
3. Bronchodilators should be optimized and edema treated cautiously with diuretics. [**C**]
4. The management of cardiovascular diseases in patients with COPD should follow existing guidelines, including routine treatment with beta-blockers. [**B**]

	Evidence	Source	QE	Overall Quality	R
1	Oxygen administration slows progression of	"Long term domiciliary," 1981	I	Good	A

	Evidence	Source	QE	Overall Quality	R
	pulmonary hypertension in hypoxic patients with COPD.	"Continuous or nocturnal," 1980 Weitzenblum et al., 1985			
2	Use diuretics with caution.	Brijker et al., 2002	II-2	Fair	C
3	Digoxin is not useful in cor pulmonale.	Brown et al., 1984 Green & Smith, 1977	II-2	Fair	D
4	Vasodilators can decrease pulmonary artery pressure but may worsen gas exchange. Long-term efficacy of calcium channel blockers is marginal and unknown for newer drugs such as sildenafil.	Agostoni et al., 1989 Barbera, Peinado, & Santos., 2003 Bratel et al., 1986 Dal Nogare & Rubin, 1986 Singh et al., 1985	II-2	Fair	D
5	Cardioselective beta-blockers do not produce adverse respiratory effects.	Salpeter, Ormiston, & Salpeter 2005	I	Good	A

QE = Quality of Evidence; R = Strength of Recommendation (See Appendix A in the original guideline document)

5.2 Mental Health (Depression and Anxiety)

Action Statement

Healthcare providers should be alert to the possibility of presence of depression in patients with COPD and treat them according to depression guidelines.

Recommendations

1. Patients with COPD should be screened for depression and anxiety using validated screening and assessment tools. [**B**]

2. Patients diagnosed with depression or anxiety should be treated with pharmacotherapy and psychotherapy suitable for patients with COPD and the patient's age. [**B**]
3. Sedative anxiolytic for the treatment of anxiety should be avoided in patients with severe COPD. [**D**]

See the VA/DoD Clinical Practice Guideline for Major Depressive Disorder.

	Evidence	Source	QE	Overall Quality	R
1	Nortriptyline, buspirone, and sertraline have been found to reduce symptoms of anxiety. Cognitive-behavioral programs that focus on relaxation and changes in thinking also produced declines in anxious symptoms.	Brenes, 2003	II	Good	B
2	Multicomponent pulmonary rehabilitation programs can result in reductions in anxious symptoms.	National Collaborating Centre for Chronic Conditions, 2004 Brenes, 2003	I	Fair	B

QE = Quality of Evidence; R = Strength of Recommendation (See Appendix A in the original guideline document)

5.3 Malnutrition

Action Statement

Malnutrition and weight loss in patients with COPD carry a poor prognosis and should be assessed and intervention considered.

Recommendations

1. BMI should be monitored in patients with COPD. [**B**]
2. Patients who are losing weight over time (BMI $\leq$21 kg/m^2) should be referred for dietary evaluation and advice. [**B**]
3. Alternate causes of weight loss associated with COPD, such as lung cancer and lung infection, should be considered. [**I**]
4. Dietary supplementation in combination with exercise and nutritional consultation should be considered in the management of patients with COPD with weight loss or malnutrition. [**B**]

	Evidence	Source	QE	Overall Quality	R
1	Malnutrition is present at all stages of COPD.	Sahebjami et al., 1993 Schols et al., 1993 Wouters & Schols, 1993	II	Good	B
2	Low BMI is associated with increased mortality in COPD.	Gray-Donald et al., 1996 Prescott et al., 2002 Schols et al., 1993	II	Fair	B
3	Weight loss in patients with COPD can be reversible.	Celli et al., 2004 Ferreira et al., 2000 Schols et al., 1998	I	Fair	B

QE = Quality of Evidence; R = Strength of Recommendation (See Appendix A in the original guideline document)

5.4 Sleep Disorders in Patients with COPD

Action Statement

All patients with COPD should be questioned about symptoms of sleep disturbance and possible associated sleep apnea syndromes, such as snoring, witnessed apnea during sleep, and excessive daytime sleepiness.

Recommendations

1. Patients with COPD should be evaluated for sleep disorders by using medical interview, which should include standardized screening questionnaires for sleep disorders (e.g., insomnia, sleep apnea). [**I**]
2. Patients complaining of insomnia should be managed in outpatient primary care and may be treated with hypnotics cautiously. [**I**]
3. Patients with other sleep-related disorders (such as sleep apnea) should be referred to a sleep specialist. [**I**]

	Evidence	Source	QE	Overall Quality	R

	Evidence	Source	QE	Overall Quality	R
1	Identify patients who may benefit from sleep evaluation.	Celli & MacNee, 2004 George & Bayliff, 2003 Klink & Quan, 1987 Kutty, 2004	III	Poor	I
2	Evaluate patients for insomnia, sleep related breathing disorders, and restless legs syndrome.	Celli, MacNee & American Thoracic Society/European Respiratory Society (ATS/ERS) Task Force, 2004 George & Bayliff, 2003 Klink & Quan, 1987 Kutty, 2004	III	Poor	I

QE = Quality of Evidence; R = Strength of Recommendation (See Appendix A in the original guideline document)

6. Special Considerations for a Patient in Need of Surgery

Action Statement

The preoperative evaluation of a patient with COPD depends upon the type and acuity of surgery and the severity of COPD.

Recommendations

Emergency Surgery

1. Emergency surgeries should not be delayed pending preoperative consultation. [**I**]

Low-Risk

2. Clinically stable patients with COPD who are undergoing minor procedures under local anesthesia do not need additional preoperative testing. [**I**]
3. Clinically stable patients with mild to moderate COPD (FEV >50 percent predicted) who are undergoing any operation under general anesthesia do not need additional preoperative testing. [**I**]

High-Risk

4. Patients with severe COPD (FEV1 <50 percent predicted) undergoing any operation that is done under general anesthesia should be considered for preoperative evaluation including pulmonary function test, gas exchange, and chest X-ray. [**I**]
5. Patients with severe COPD (FEV <50 percent predicted) planned for high-risk surgery should be referred to a pulmonary specialist. [**I**]

Optimization of Pre- and Postoperative Care

6. Bronchodilator therapy should be optimized prior to planned surgery. [**I**]
7. Patients should be encouraged to quit smoking and instructed to stop smoking at least 6 to 8 weeks before surgery. [**I**]
8. Deep breathing, incentive spirometry, early mobilization, and adequate pain control should be encouraged to reduce postoperative pulmonary complications in patients with COPD. [**I**]
9. Patients who are on oral glucocorticoids should receive stress doses of intravenous glucocorticoids in the perioperative period to reduce the risk of adrenal insufficiency. [**I**]
10. Pulmonary consultation should be obtained prior to surgery in patients with an FEV1 below 35 percent predicted and in patients who are to undergo lung volume reduction surgery. [**I**]

7. Planning Air Travel for a Patient with Stable COPD

Action Statement

Patients with severe COPD who are on long-term oxygen therapy or have sea level PO_2 below 80 mm Hg should be evaluated pre-flight for supplementary oxygen during air travel. [**C**]

Recommendations

1. Perform pre-flight estimation of the expected degree of hypoxemia. [**C**]
2. Prescribe sufficient oxygen in flight to raise PO_2 (Alt) to around ~60 mm Hg. [**C**]
3. Warn patients with known bullous disease of the increased risk for pneumothorax during air travel. [**C**]
4. Arrange in-flight O_2 supplementation with the airline.

The expected in-flight PO_2 values may be calculated using the steps outlined in Table 10 in the original guideline document or may be looked up in Table 11 in the original guideline document.

	Evidence	Source	QE	Overall Quality	R
1	Patients with COPD during flight may develop severe hypoxemia or symptoms and right heart failure resulting in urgent requests for oxygen and can affect morbidity and mortality.	Christensen et al., 2000 Dillard, Beninati, & Berg, 1991 Speizer et al., 1989	II-b	Fair	C
2	Predicting PaO_2 at altitude from PaO_2 at ground level.	Dillard et al., 1989 Dillard, Rosenberg, & Berg 1993 Dillard et al., 1995	II-b	Fair	C
3	LTOT patients should increase flow by one to 2 liter/minute during flight.	Gong, 1992	II-b	Fair	C

QE = Quality of Evidence; R = Strength of Recommendation (See Appendix A in the original guideline document)

8. Follow- Up Monitoring

8.1 Schedule follow-up

Action Statement

Patients with moderate to severe COPD should be reevaluated at least once a year. [**I**]

Recommendations

1. Patients with COPD should be assessed on a periodic basis, based on the severity and progression of their disease. [**I**]
2. Periodic evaluations of patients with COPD should include a review of their symptoms, their current treatment regimen, reported exacerbations, and spirometry testing. [**I**]

8.2 Palliative Care

Action Statement

Healthcare providers should assist patients with COPD and their families during stable periods of health to promote discussion about advanced care planning, including end-of-life care. [**I**]

The clinical care team will provide regular, ongoing assessments of distressing symptoms (especially dyspnea) and actively seek to relieve suffering through a comprehensive approach to the physical, psychological, social, and spiritual aspects. [**I**]

Recommendations

1. Healthcare providers should assess the needs of patients with COPD and their families for advanced care planning and initiate advanced care in patients with poor prognosis (e.g., hospitalized with exacerbations). [**I**]
2. Patients with COPD and their families should be encouraged to participate in the planning and management of their treatment to improve their ability to cope with COPD in the future. [**I**]
3. The referral of the patient and their family to appropriate expertise in palliative care to assist in the relief of suffering may be considered when the patient/family's needs require such or are otherwise indicated. [**I**]

Module B : Management of COPD Acute Exacerbation

9. Definition of Acute Exacerbations

An exacerbation is a sustained worsening of the patient's respiratory symptoms and function from his or her usual stable state that is beyond normal day-to-day variations, and is acute in onset. Commonly reported symptoms are worse breathlessness, cough, increased sputum production, and change in sputum color. The change in the patient's condition often necessitates a change in medication.

10. Referral to the Emergency Department

10.1 Criteria for Referring to the Emergency Department/Hospital

Action Statement

More severe exacerbation or inadequate resources in the outpatient setting may require evaluation and management of the patient in the emergency department or a hospital setting. [**I**]

Recommendations

1. Patients evaluated for acute exacerbation of COPD should be considered for referral to the emergency department or admission to the hospital if they present with any of the following indications [**I**]:

a. Unstable vital signs
b. Impaired level of consciousness or altered mental status
c. Severe breathlessness
d. New or worsening hypoxemia (SaO_2 <90 percent)
e. Inadequate disease management resources at home
f. Lack of appropriate resources to evaluate or manage the patient in a clinic setting

10.2 Initiation of Short-Acting Bronchodilator and/or Oxygen Therapy if Necessary

Action Statement

Early initiation of bronchodilator therapy and oxygen (in hypoxemic patients) is appropriate prior to full assessment and treatment in the emergency department or hospital.

Recommendations

1. Initial treatment for patients experiencing an initial acute exacerbation of COPD who have been referred to the emergency department or admitted directly to the hospital should include [**I**]:
    a. Short-acting bronchodilator, by nebulizer or metered dose inhaler, if readily available
    b. Low flow oxygen therapy to maintain SAO_2 at 90 percent

See section 10.3 of the original guideline document for recommended emergency department evaluations.

11. **Management of Acute Exacerbation in the Outpatient Setting**

11.1 Assessment, Testing, and Diagnosis

Action Statement

Patients with COPD with acute exacerbation should be assessed to confirm the diagnosis, rule out other causes for worsening symptoms, and determine the severity of the exacerbation and the priorities for treatment.

Recommendations

Clinical assessment should include:

1. The diagnosis of acute exacerbation of COPD should be confirmed and other causes excluded based upon clinical evaluation with additional diagnostic tests in selected cases. [**I**]
2. The severity of an exacerbation of COPD should be determined based upon medical history, symptoms, physical examination, and pulmonary function tests. [**I**]
3. Medical history with a patient with acute exacerbation should include:

a. Onset, duration, and type of symptoms (cough, sputum production, dyspnea, fever, decreased exercise tolerance, confusion, or acute mental status changes)
b. Current medication use
c. History of prior COPD exacerbations or hospitalizations (frequency, intensive care unit [ICU] admissions, and prior intubation)
d. The severity of the underlying COPD
e. Presence of comorbid conditions; e.g., heart disease.

4. Physical examination with a patient with acute exacerbation should include:
    a. Vital signs
    b. Level of consciousness
    c. A careful pulmonary examination
    d. Cardiovascular examination
    e. Oxygenation

5. Laboratory testing that may be considered with a patient with acute exacerbation:
    a. Oximetry (in all patients with moderate or worse COPD)
    b. Arterial blood gas in patients with deteriorating clinical status
    c. Spirometry, if available, in patients who are able to perform the test and for whom there is baseline data available for comparison
    d. Chest X-ray to exclude other causes if clinically suspected
    e. ECG if clinically indicated

6. Alternative causes of increased symptoms that need to be clinically excluded include:
    a. Congestive heart failure
    b. Pneumonia
    c. Pneumothorax
    d. Pulmonary embolism
    e. Cardiac ischemia
    f. Cardiac arrhythmia
    g. Upper airway infection; e.g., acute sinusitis
    h. Upper airway obstruction
    i. Pleural effusion
    j. Recurrent aspiration
    k. Noncompliance with medications
    l. Inappropriate oxygen therapy
    m. Adverse effects of medications; e.g., sedatives

12. **Pharmacotherapy for Acute Exacerbation in Outpatient Settings**

12.1 Bronchodilators

Action Statement

Provide relief of symptoms and improve FEV1 with short-acting inhaled bronchodilator therapy. [**B**]

Recommendations

1. A short-acting bronchodilator (short-acting anticholinergic or short-acting beta 2-agonist) or a combination of both, using a metered dose inhaler with a spacer or aerosol mobilization, should be administered as soon as possible and as frequently as necessary. The choice of agent should be made on the basis of individual assessment and initial response to therapy. [**B**]
2. Methylxanthines should be avoided either orally or systemically since these agents may lead to side effects and have no proven efficacy in the setting of an acute exacerbation of COPD. [**D**]

	Evidence	Source	QE	Overall Quality	Net Effect	R
1	Ipratropium and albuterol, alone and in combination, demonstrated improvement in FEV1, with no difference between therapies.	Bach et al., 2001	I	Fair	Substantial	B
2	A methylxanthine (such as aminophylline) added to ipratropium and albuterol, alone and in combination, increased side effects.	Bach et al., 2001	I	Fair	Substantial	D

QE = Quality of Evidence; R = Strength of Recommendation (See Appendix A in the original guideline document)

12.2 Antibiotics

Action Statement

Prescribe a course of antibiotics for acute exacerbation of COPD if symptoms indicate bacterial infection; choice of antibiotic agent may be based on the degree of complication (number of exacerbations, FEV1, previous exposure to antibiotics, and cardiac disease).

Recommendations

1. COPD patients with acute exacerbation of COPD with at least two of the following will most likely benefit from antibiotic therapy [**A**]:
    a. Increased sputum purulence (change in sputum color)
    b. Increased sputum volume
    c. Increased dyspnea

2. Choice of antibiotic agents may be determined based on local bacterial resistance patterns. [**C**]

3. Choice of antibiotic agents may be determined based on the frequency of exacerbations in the past 12 months, severity of underlying COPD, presence of cardiac disease, and recent (within 3 months) antibiotic exposure for each patient. [**B**]
4. For uncomplicated exacerbations of COPD, consider doxycycline, trimethoprim/sulfamethoxazole, second generation cephalosporin. [**C**]
5. For complicated exacerbations of COPD, consider beta-lactam/beta-lactamase inhibitor or fluoroquinolone. [**C**]

Stratifying the patient as complicated or uncomplicated may be helpful in determining the choice of antibiotic and is summarized in Table 5 below.

Table 5: Determine Level of Patient Complication and Antibiotic Agents

Patient Characteristics	Antibiotic Agents
Uncomplicated Patients 1. Have experienced less than 3 exacerbations in the past 12 months 2. Have a baseline FEV1 of >50% predicted 3. Do not have cardiac disease 4. Have not been exposed to antibiotics in the past 3 months	• Doxycycline • Trimethoprim/Sulfamethoxazole • Second or third generation cephalosporin • Extended spectrum macrolide
Complicated Patients 1. Have experienced 3 or more exacerbations in the past 12 months 2. Have a baseline FEV1 of <50% predicted 3. Have cardiac disease 4. Have been exposed to antibiotics in the	• Beta-lactam/beta-lactamase inhibitor • Fluoroquinolone*

Patient Characteristics	Antibiotic Agents
past 3 months	
** By explicitly defining the patient that would benefit from the use of quinolone, the use of these drugs in uncomplicated exacerbations is discouraged.*	

	Evidence	Source	QE	Overall Quality	R
1	Identify presence of symptoms that may indicate bacterial infection.	Anthonisen et al., 1987 Stockley et al., 2000	I	Good	A
2	Patients with COPD and acute exacerbation who have at least 2 of the following symptoms will benefit from antibiotic therapy: • Increased dyspnea • Increased sputum volume • Increased sputum purulence	Anthonisen et al., 1987 Ram et al., 2006	I	Good	A
3	Do not perform sputum culture in primary care (outpatient) setting for establishing the bacteriological cause of COPD exacerbation.	Celli & MacNee, 2004 National Collaborating Centre for Chronic Conditions, 2004	III	Good	D
4	Start a course of antibiotics in patients with acute exacerbation of COPD and symptoms indicative of bacterial infection.	Allegra et al., 2001 Anthonisen et al., 1987 Nouira et al., 2001 Ram et al., 2006 Saint et al.,	I	Good	A

	Evidence	Source	QE	Overall Quality	R
		1995			
5	Base antibiotic choice on the local bacterial resistance patterns (if available)	Celli & MacNee, 2004 Grossman et al., 2006 National Collaborating Centre for Chronic Conditions, 2004	I	Fair	C
6	Stratify patients into uncomplicated and complicated to assist in antibiotic choice	Martinez et al., 2005 Miravitlles, Murio, & Guerrero., 2001 O'Donnell et al., 2003	I	Fair	B
7	For uncomplicated exacerbations of COPD, consider the following antibiotics: • Doxycycline • Trimethoprim/sulfamethoxazole • Second generation cephalosporin • Extended spectrum macrolide ketolide	Celli & MacNee, 2004 National Collaborating Centre for Chronic Conditions, 2004	III	Fair	C
8	For complicated exacerbations of COPD, consider the following antibiotics: • Beta-lactam/beta-lactamase inhibitor • Fluoroquinolone	Martinez et al., 2005 Wilson et al., 2002, 2004, 2006	I	Fair	B

QE = Quality of Evidence; R = Strength of Recommendation (See Appendix A in the original guideline document)

12.3 Oral Glucocorticoids

Action Statement

Consider a course of oral glucocorticoids in the treatment of an acute exacerbation of COPD to improve outcomes. [**A**]

Recommendations

1. A short course of oral glucocorticoids with a dose equivalent to 30 to 40 mg of prednisone per day (up to 14 days) should be considered for patients with COPD exacerbation. [**A**]

	Evidence	Source	QE	Overall Quality	R
1	Short-term treatment (up to 14 days) with systemic glucocorticoids results in greater improvement in FEV1 compared to placebo.	Aaron et al.,2003 Albert, Martin, & Lewis, 1980 Davies, Angus, & Calvery, 1999 Maltais et al., 2002 Niewoehner et al., 1999 Walters, Walters & Wood-Baker., 2005 Wood-Baker et al., 2005	I	Fair	B
2	The 30-day relapse rate is lower in glucocorticoid treated patients compared to placebo	Aaron et al., 2003 Niewoehner et al., 1999 Wood-Baker et al., 2005	I	Good	A
3	Duration of hospitalization is approximately one to 2 days shorter in glucocorticoid treated patients compared to placebo	Davies, Angus, & Calvery, 1999 Maltais et al., 2002 Niewoehner et al., 1999 Wood-Baker et	I	Good	A

	Evidence	Source	QE	Overall Quality	R
		al., 2005			
4	There was no significant difference in mortality between glucocorticoid treated patients compared to placebo.	Wood-Baker et al., 2005	I	Good	A
5	Glucocorticoid treated patients had greater improvement in dyspnea compared to placebo.	Aaron et al., 2003 Maltais et al., 2002 Thompson et al., 1996 Wood-Baker et al., 2005	I	Good	A
6	In emergency department based studies, numerically fewer patients receiving glucocorticoids required hospital admission compared to placebo.	Aaron et al., 2003 Wood-Baker et al., 2005 Thompson et al., 1996	I	Good	A
7	Hyperglycemia was more common in patients receiving glucocorticoids compared to placebo.	Albert, Martin, & Lewis, 1980 Davies, Angus, & Calvery, 1999 Maltais et al., 2002 Niewoehner et al., 1999 Wood-Baker et al., 2005	I	Good	A

QE = Quality of Evidence; R = Strength of Recommendation (See Appendix A in the original guideline document)

13. **Follow-Up**

Recommendations

1. Patients should be instructed that if they have not improved with therapy over 48 to 72 hours or if they deteriorate at any time, they should seek attention from a healthcare provider. [**I**]

Module C: Pharmacotherapy

See also Appendix C of the original guideline document for recommended pharmacotherapy.

14. **Bronchodilators**

14.1 Short-Acting Bronchodilators in Patients with COPD

Action Statement

Consider using a maintenance short-acting anticholinergic and/or a maintenance short-acting beta 2-agonist in patients whose symptoms adequately respond to these drugs. Educate patient about the use of inhaler devices.

Recommendations

1. Short-acting beta 2-agonists should be used as rescue therapy as needed. [**A**]
2. Short-acting bronchodilators may be considered for maintenance for patients with COPD, as follows:
    a. Short-acting anticholinergics (SAAC) or short-acting beta 2-agonists (SABA) to improve FEV1 and respiratory symptoms and reduce frequency of exacerbations [**B**]
    b. SAAC to improve quality of life (QOL) [**B**]
    c. Insufficient evidence for SABA to improve QOL [**I**]

3. Since all chlorofluorocarbons (CFC) aerosols must be phased out, ipratropium CFC has been replaced by ipratropium hydrofluoroalkane (HFA). These two preparations may be considered in usual doses to improve FEV1 in patients with COPD. [**B**]

	Evidence	Source	QE	Overall Quality	Net Effect	R
1	Ipratropium improved FEV1 and respiratory symptoms compared to placebo. When placebo was used, a short-acting inhaled beta 2-agonist was used as rescue therapy.	Dahl et al., 2001 Mahler et al., 1999 Wadbo et al., 2002	I	Good	Substantial for FEV1 Moderate for symptoms	B
2	Ipratropium improved QOL compared to	Dahl et al., 2001	I	Good	Moderate	B

	Evidence	Source	QE	Overall Quality	Net Effect	R
	placebo or maintenance albuterol.	Friedman et al., 1999 Mahler et al., 1999 Rennard et al., 2001				
3	Ipratropium was equivalent to maintenance albuterol for FEV1.	Friedman et al., 1999	I	Good	Substantial	C
4	Short-acting beta 2-agonists improve FEV1, respiratory symptoms, and reduce exacerbations.	Donohue et al., 2006 Nair et al., 2005 Sestini et al., 2002	I	Good	Moderate	B
5	HFA ipratropium is equivalent to CFC for FEV1.	Brazinsky et al., 2003 Taylor et al., 2001	I	Fair	Substantial	B

QE = Quality of Evidence; R = Strength of Recommendation (See Appendix A in the original guideline document)

14.2 Long-Acting Inhaled Beta 2-Agonists in Patients with COPD

Action Statement

Consider using a long-acting inhaled beta 2-agonist (LABA) to improve QOL or respiratory symptoms such as dyspnea [**A**], and to reduce exacerbations [**C**]. Educate patient about the use of inhaler devices.

Recommendations

1. Long-acting inhaled beta 2-agonists (LABA) should be considered for patients with COPD with an FEV1 70 percent predicted or less to:
    a. Improve FEV1 [**B**]
    b. Improve persistent respiratory symptoms such as dyspnea, or impaired health-related QOL [**A**]
    c. Reduce exacerbations in patients who have had at least one exacerbation in the previous year and required glucocorticoids, antibiotics, or hospitalization [**C**]

2. In general, a long-acting inhaled beta 2-agonist (LABA) should not be substituted for a SAAC with the expectation of improving respiratory symptoms, QOL, or exacerbations. [**B**]

	Evidence	Source	QE	Overall Quality	Net Effect	R
1	LABA (formoterol or salmeterol) improved FEV1 compared to placebo	Aalbers et al., 2002 Appleton et al., 2006 Brusasco et al., 2003 Calverley et al., "Maintenance therapy," 2003 Calverley et al., "Combined salmeterol and fluticasone," 2003 Dahl et al., 2001 Hanania et al., 2003 Mahler et al., 1999; 2002 Rennard et al., 2001 Rossi et al., 2002 Stockley, Chopra, & Rice, 2006 Stockley, Whitehead, & Williams, 2006 Szafranski et al., 2003	I	Fair	Substantial	B

	Evidence	Source	QE	Overall Quality	Net Effect	R
		van Noord et al., 2000 Wadbo et al., 2002				
2	LABA (formoterol or salmeterol) improved respiratory symptoms compared to placebo.	Aalbers et al., 2002 Brusasco et al., 2003 Calverley et al., "Maintenance therapy," 2003 Calverley et al., "Combined salmeterol and fluticasone," 2003 Dahl et al., 2001 Hanania et al., 2003 Mahler et al., 1999 Rossi et al., 2002 Stockley, Chopra, & Rice, 2006 Stockley, Whitehead, & Williams, 2006 Szafranski et al., 2003 van Noord et al., 2000 Wadbo et al., 2002	I	Good	Substantial	A

	Evidence	Source	QE	Overall Quality	Net Effect	R
3	Formoterol improved QOL	Calverley et al., "Maintenance therapy," 2003 Dahl et al., 2001 Rossi et al., 2002 Szafranski et al., 2003	I	Good	Substantial	A
4	Salmeterol improved QOL and reduced exacerbations.	Appleton et al., 2006 Calverley et al., "Combined salmeterol and fluticasone," 2003 Stockley, Chopra, & Rice, 2006 Stockley, Whitehead, & Williams, 2006	I	Good	Small	C
5	Formoterol or salmeterol inconsistently improved FEV1, QOL, and respiratory symptoms compared to ipratropium, with little or no improvement in exacerbations.	Dahl et al., 2001 Mahler et al., 1999 Rennard et al., 2001 Wadbo et al., 2002	I	Good	Small	C

QE = Quality of Evidence; R = Strength of Recommendation (See Appendix A in the original guideline document)

14.3 Long-Acting Inhaled Anticholinergics in Patients with COPD

Action Statement

Consider using a long-acting inhaled anticholinergic (LAAC) in patients with COPD to improve respiratory symptoms and QOL or reduce moderate to severe exacerbations [**A**]; or to improve FEV1 or reduce hospitalizations [**B**].

Recommendations

1. Long-acting anticholinergics (LAAC), compared to placebo or maintenance SAAC, should be considered for patients with COPD and an FEV1 65 percent predicted or less to:
    a. Improve persistent respiratory symptoms such as dyspnea or impaired QOL [**A**]
    b. Reduce moderate to severe COPD exacerbations (i.e., exacerbations requiring antibiotics and/or oral or systemic glucocorticoids) [**A**]
    c. Reduce COPD-related hospitalizations [**B**]

2. When a LAAC is used to improve patient outcomes in patients taking a SAAC, the SAAC should be discontinued. [**I**] However, the use of a SABA as needed for rescue therapy should be continued.
3. In choosing long-acting bronchodilators, both LAAC and LABA provide similar benefits; however, there may be more modest improvement in FEV1 with LAAC. [**B**]

	Evidence	Source	QE	Overall Quality	Net Effect	R
1	Tiotropium improved QOL, dyspnea, or exacerbations compared to placebo and maintenance ipratropium.	Barr et al., 2005 Barr et al, 2006 Dusser, Bravo, & Iacono, 2006 Niewoehner et al., 2005	I	Good	Substantial	A
2	Tiotropium improved FEV1, or hospitalizations compared to placebo and maintenance ipratropium.	Barr et al., 2005 Niewoehner et al., 2005	I	Fair	Moderate	B
3	Tiotropium improved FEV1 compared to salmeterol or formoterol.	Barr et al., 2005 Briggs et al., 2005 Van Noord et al., 2005	I	Fair	Small	C

	Evidence	Source	QE	Overall Quality	Net Effect	R
4	Tiotropium did not significantly improve dyspnea, QOL, exacerbations, or hospitalizations compared to salmeterol.	Barr et al., 2005 Barr et al, 2006 Briggs et al., 2005 Oostenbrink et al., 2005	I	Good	Small	C

QE = Quality of Evidence; R = Strength of Recommendation (See Appendix A in the original guideline document)

15. **Combination of Inhaled Bronchodilators**

Action Statement

Combination bronchodilator therapy may be considered for patients with inadequate response to single agents to improve FEV1 and to reduce symptoms and/or exacerbations. [**B**]

Recommendations

1. When response to therapy with a SABA is inadequate, consider the use of regularly scheduled combination SABA + SAAC to improve FEV1 and reduce exacerbations compared to treatment with the individual components. [**B**]
2. When response to regularly scheduled SAAC or combination of SABA + SAAC is inadequate, consider the use of combination SAAC + LABA to improve FEV1 and symptoms and reduce exacerbations compared to treatment with the individual components. [**B**]
3. When response to a LABA + SAAC or a LAAC alone is inadequate, consider the use of combination LABA + LAAC to improve FEV1. [**B**]
4. Consider the use of theophylline in addition to short-acting bronchodilators to improve FEV1. [**B**]
5. Consider the use of theophylline in addition to LABA to improve FEV1, symptoms, and QOL compared to therapy with the individual components. [**B**]
6. There is insufficient evidence to recommend that certain combinations are superior to other combinations, monotherapy with LAAC, or regimens including an inhaled glucocorticoid. Therefore, treatment selection should be based on patient-specific variables. [**I**]

	Evidence	Source	QE	Overall Quality	Net Effect	R
1	Combination SABA + SAAC improved FEV1	Campbell, 1999	I	Fair	Moderate	B

	Evidence	Source	QE	Overall Quality	Net Effect	R
	and decreased exacerbations.	"In chronic," 1994 "Routine," 1997 Friedman et al., 1999 Gross et al., 1998				
2	Combination LABA + SAAC caused improvement in FEV1 and a trend in decreased exacerbations and improved symptoms.	Appleton et al., 2006 Chapman et al., 2002 D'Urzo et al., 2001 Van Noord et al., 2000	I	Fair	Moderate	B
3	Combination LABA + LAAC provided greater improvement in pulmonary function than either agent alone.	van Noord et al., 2000 van Noord et al., 2006	I	Fair	Moderate	B
4	Combination short-acting agents and theophylline provided greater improvement in pulmonary function than either agent alone.	Nishimura et al., 1993 Nishimura et al., 1995	I	Fair	Moderate	B
5	Combination LABA and theophylline improved FEV1.	ZuWallack et al., 2001	I	Good	Moderate	B

QE = Quality of Evidence; R = Strength of Recommendation (See Appendix A in the original guideline document)

16. **Inhaled Glucocorticoids**

Action Statement

Consider adding inhaled glucocorticoids to optimize bronchodilator therapy in patients with COPD who have both severe disease (FEV1 <50 percent predicted) and who have had at least one exacerbation in the prior year, to reduce the frequency of exacerbations. [**A**]

Alternatively, consider adding inhaled glucocorticoids in patients with severe COPD (FEV1 <50 percent predicted) to improve FEV1, respiratory symptoms, and QOL. [**B**]

Recommendations

1. Inhaled glucocorticoids are not recommended in patients with mild to moderate COPD (FEV1 $\geq$50 percent predicted) as there is little evidence of efficacy. [**D**]
2. Combination of a LABA and inhaled glucocorticoid may be considered in patients with severe COPD and at least one COPD exacerbation in the prior year to decrease the incidence of COPD exacerbations compared to therapy with the individual components. [**A**]
3. Combination of a LABA and inhaled glucocorticoid can be used in symptomatic patients with severe COPD to improve FEV1 (approximately 0 to 100 mL), symptoms, and/or QOL. [**B**]
4. There is insufficient evidence to recommend a specific choice or optimal dose when starting treatment with inhaled glucocorticoids. The doses used in efficacy trials (fluticasone propionate 500 micrograms twice a day [bid], budesonide 400 micrograms bid) or equivalent dosages are recommended. [**I**]
5. Once treatment with inhaled glucocorticoids has been initiated, it is recommended to use caution when stopping the medication, as discontinuation may lead to COPD exacerbation. [**B**]
6. Patients should be informed about the potential side effects of inhaled glucocorticoids (oral candidiasis, bruising, adrenal suppression, cataracts, and osteoporosis). [**B**]
7. Treatment with inhaled glucocorticoids does not significantly affect the rate of decline in FEV1. [**C**]
8. Patients with COPD who are receiving oral or inhaled glucocorticoids should be evaluated for bone loss and considered for prevention or treatment of osteoporosis. [**I**]
9. The risks of long-term treatment with glucocorticoids should be discussed with the patient. [**I**]

	Evidence	Source	QE	Overall Quality	Net Effect	R
1	In moderate to severe COPD, inhaled glucocorticoids decrease exacerbations (~20 to 30 percent) and can cause a small increase in FEV1 (<100 mL) and improve symptoms and QOL.	Alsaedi, Sin, & McAlister, 2002 Bourbeau, Rouleau, & Boucher, 1998 Burge et al., 2003 Calverley et al., "Maintenance therapy," 2003	I	Good	Substantial decrease in exacerbations	A
					Moderate improvement in FEV1 Improvement in symptoms and QOL	C

	Evidence	Source	QE	Overall Quality	Net Effect	R
		Calverley et al., "Combined salmeterol and fluticasone," 2003 Calverley et al., 2007 Hanania et al., 2003 Jones et al., 2003 Kardos et al., 2007 Lofdahl et al., 2005 Mahler et al., 2002 Paggiaro et al., 1998 Pauwels et al., 1999 Sin et al., 2003 Szafranski et al., 2003 "Effect of inhaled triamcinolone," 2000 Vestbo et al., 1999 Weir et al., 1999				
2	Inhaled glucocorticoids have no effect on exacerbation rate in	Alsaedi, Sin, & McAlister, 2002	I	Good	Negligible	D

	Evidence	Source	QE	Overall Quality	Net Effect	R
	mild to moderate COPD.	Gartlehner et al., 2006 Jones et al., 2003 Pauwels et al., 1999 Sin et al., 2003 "Effect of inhaled triamcinolone," 2000 Vestbo et al., 1999				
3	Withdrawal of inhaled glucocorticoids can lead to exacerbations.	Van der Valk et al., 2002 Wouters et al., 2005	I	Good	Moderate	B
4	Glucocorticoids produce many side effects.	"Effect of inhaled triamcinolone," 2000	I	Good	Moderate	B
5	Inhaled glucocorticoids do not significantly affect the rate of decline in FEV1.	Highland, Strange, & Heffner, 2003 Sutherland et al., 2003	I	Good	Negligible	C

QE = Quality of Evidence; R = Strength of Recommendation (See Appendix A in the original guideline document)

17. **Theophylline**

Action Statement

Theophylline can be added to improve pulmonary function, symptoms, or activities in patients with COPD who do not achieve adequate symptom control with inhaled bronchodilators. [**A**]

Recommendations

1. Patients with COPD who do not achieve adequate symptom control with inhaled bronchodilators may be considered for adding theophylline therapy with an initial dose of 400 to 600 mg/day and a therapeutic target of blood level in the range 5 to 12 micrograms/mL. [**A**]
2. Blood levels should be carefully measured after initiation or change in dose. [**I**]
3. After the initial stability, repeat levels should be obtained when symptoms change, acute illness develops, potentially interacting drugs are added, noncompliance is suspected, dose adjustments are made, or symptoms suggestive of toxicity develop. [**I**]
4. If benefit has been demonstrated with a higher blood level (15 micrograms/mL of theophylline), careful monitoring is required. The risk-to-benefit ratio increases above a concentration of 12 micrograms/mL, especially in older patients. [**B**]
5. Drug interactions with theophylline are common and may either increase or decrease theophylline metabolism. All changes in medical regimens should be evaluated for potential impact on theophylline levels. [**C**]
6. Theophylline should be continued only in patients who demonstrate a symptomatic benefit, such as improved dyspnea or exercise tolerance. The improvement in function from theophylline may not be evident in pulmonary function testing. However, therapy should be discontinued in patients who demonstrate no subjective or objective improvement after several weeks of theophylline therapy. [**D**]

	Evidence	Source	QE	Overall Quality	R
1	Improvement in FEV1 and FVC and symptoms in favor of the theophylline group compared to placebo.	Chen et al., 2005 Ram et al., 2002 Ram, 2006 Rossi et al., 2002 Zhou et al., 2006	I	Good	B
2	Combination treatment with salmeterol + theophylline increased FEV1 and reduced dyspnea better than either alone, but is associated with an increased incidence of gastrointestinal side effects.	ZuWallack et al., 2001	I	Good	B
3	Theophylline may prevent exacerbations.	Rossi et al., 2002	I	Good	B
4	Theophylline has no	Barr, Rowe, &	I	Fair	D

	Evidence	Source	QE	Overall Quality	R
	benefit in treatment of COPD exacerbations and increased adverse effects.	Camargo, 2003			

QE = Quality of Evidence; R = Strength of Recommendation (See Appendix A in the original guideline document)

Definitions:

Quality of Evidence

I	At least one properly done randomized controlled trial (RCT)
II-1	Well designed controlled trial without randomization
II-2	Well designed cohort or case-control analytic study
II-3	Multiple time series, dramatic results of uncontrolled experiment
III	Opinion of respected authorities, case reports, and expert committees

Overall Quality

Good	High grade evidence (I or II-1) directly linked to health outcome
Fair	High grade evidence (I or II-1) linked to intermediate outcome; or grade evidence (II-2 or II-3) directly linked to health outcome
Poor	Level III evidence or no linkage of evidence to health outcome

Net Effect of the Intervention

Substantial	More than a small relative impact on a frequent condition with a substantial burden of suffering or A large impact on an infrequent condition with a significant impact on the individual patient level.
Moderate	A small relative impact on a frequent condition with a substantial burden of suffering or A moderate impact on an infrequent condition with a significant impact on the individual patient level.
Small	A negligible relative impact on a frequent condition with a substantial burden of suffering or A small impact on an infrequent condition with a significant impact on the individual patient level.
Zero or	Negative impact on patients

Negative	or No relative impact on either a frequent condition with a substantial burden of suffering; or an infrequent condition with a significant impact on the individual patient level.

Strength of Recommendation

	Net Benefit of the Intervention			
Quality of Evidence	**Substantial**	**Moderate**	**Small**	**Zero or Negative**
Good	A	B	C	D
Fair	B	B	C	D
Poor	I	I	I	I

Evidence Rating System

A	A strong recommendation that the clinicians provide the intervention to eligible patients. *Good evidence was found that the intervention improves important health outcomes and concludes that benefits substantially outweigh harm.*
B	A recommendation that clinicians provide (the service) to eligible patients. *At least fair evidence was found that the intervention improves health outcomes and concludes that benefits outweigh harm.*
C	No recommendation for or against the routine provision of the intervention is made. *At least fair evidence was found that the intervention can improve health outcomes, but concludes that the balance of benefits and harms is too close to justify a general recommendation.*
D	Recommendation is made against routinely providing the intervention to asymptomatic patients. *At least fair evidence was found that the intervention is ineffective or that harms outweigh benefits.*
I	The conclusion is that the evidence is insufficient to recommend for or against routinely providing the intervention. *Evidence that the intervention is effective is lacking, or poor quality, or conflicting, and the balance of benefits and harms cannot be determined.*

Where existing literature was ambiguous or conflicting, or where scientific data were lacking on an issue, recommendations were based on the clinical experience of the Working Group. These recommendations are indicated in the evidence tables as based on "Working Group Consensus" and given the grade [**I**].

Abbreviations and Acronyms List

AAT Alpha-1-Antitrypsin
bid Twice a day
BMI Body Mass Index
BODE The Body Mass Index Airflow Obstruction, Dyspnea, Exercise Performance Index
CFC Chlorofluorocarbons
COPD Chronic Obstructive Pulmonary Disease
CRDQ Chronic Respiratory Disease Questionnaire
CT Computed Tomography
DLCO Carbon Monoxide Diffusing Capacity
ECG Electrocardiogram
FEV1 Forced Expiratory Volume in One Second
FVC Forced Vital Capacity
HFA Hydrofluoroalkane
LAAC Long-Acting Anticholinergic
LABA Long-Acting Inhaled Beta 2-Agonist
LTOT Long-Term Oxygen Therapy
LVRS Long Volume Reduction Surgery
MMRC Modified Medical Research Council
NAC N-Acetylcysteine
PPV Pneumococcal Polysaccharide Vaccine
QOL Quality of Life
SAAC Short-Acting Anticholinergic
SABA Short-Acting Beta 2-Agonist
VC Vital Capacity

CLINICAL ALGORITHM(S)

The following are available:

- Module A: Management of COPD
- Module B: Acute Exacerbation

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The algorithm and annotations are based on an exhaustive review of the literature. The goal of the literature review is to provide a systematic basis for the development of an evidence-based guideline. The literature search is followed by

critical analysis of the literature, primarily by the clinical experts. To promote an evidence-type approach, the quality of evidence is rated using a hierarchical rating scheme. The value of a hierarchical rating scheme is that it provides a systematic means for evaluating the scientific basis for health care services.

The type of supporting evidence is identified for selected recommendations (see the "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate management of outpatient chronic obstructive pulmonary disease

POTENTIAL HARMS

- Side effects of pharmacotherapy (see Table C6 in the original guideline document for cautions and special instruction for selected chronic obstructive pulmonary disease drug therapy)
- There is the potential for serious morbidity and mortality all surgical treatments for chronic obstructive pulmonary disease (COPD).

CONTRAINDICATIONS

CONTRAINDICATIONS

Influenza Vaccine

An annual influenza vaccination is recommended for individuals with chronic obstructive pulmonary disease (COPD) unless contraindicated due to severe anaphylactic hypersensitivity to egg protein.

Short-acting Bronchodilators

The use of beta 2-agonists is contraindicated in patients with unstable arrhythmia or angina.

Lung Transplantation Surgery

Relative Contraindications

- Age older than 65 years. Older patients have less optimal survival, likely due to comorbidities, and therefore, recipient age should be a factor in candidate selection. Although there cannot be endorsement of an upper age limit as an absolute contraindication (recognizing that advancing age alone in an otherwise acceptable candidate with few comorbidities does not necessarily compromise successful transplant outcomes), the presence of several relative contraindications can combine to increase the risks of transplantation above a safe threshold.

- Critical or unstable clinical condition (e.g., shock, mechanical ventilation or extra-corporeal membrane oxygenation)
- Severely limited functional status with poor rehabilitation potential
- Colonization with highly resistant or highly virulent bacteria, fungi, or mycobacteria
- Severe obesity defined as a body mass index (BMI) exceeding 30 kg/m^2
- Severe or symptomatic osteoporosis
- Mechanical ventilation. Carefully selected candidates on mechanical ventilation without other acute or chronic organ dysfunction, who are able to actively participate in a meaningful rehabilitation program, may be successfully transplanted.
- Other medical conditions that have not resulted in end-stage organ damage, such as diabetes mellitus, systemic hypertension, peptic ulcer disease, or gastroesophageal reflux should be optimally treated before transplantation. Patients with coronary artery disease may undergo percutaneous intervention before transplantation or coronary artery bypass grafting concurrent with the procedure.

Absolute Contraindications

- Malignancy in the last 2 years, with the exception of cutaneous squamous and basal cell tumors. In general, a 5-year disease-free interval is prudent. The role of lung transplantation for localized bronchoalveolar cell carcinoma remains controversial.
- Untreatable advanced dysfunction of another major organ system (e.g., heart, liver, or kidney). Coronary artery disease not amenable to percutaneous intervention or bypass grafting, or associated with significant impairment of left ventricular function, is an absolute contraindication to lung transplantation, but heart-lung transplantation could be considered in highly selected cases.
- Non-curable chronic extrapulmonary infection including chronic active viral hepatitis B, hepatitis C, and human immunodeficiency virus
- Significant chest wall/spinal deformity
- Documented nonadherence or inability to follow through with medical therapy or office follow-up, or both
- Untreatable psychiatric or psychologic condition associated with the inability to cooperate or comply with medical therapy
- Absence of a consistent or reliable social support system
- Substance addiction (e.g., alcohol, tobacco, or narcotics) that is either active or within the last 6 months

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The Department of Veterans Affairs (VA) and The Department of Defense (DoD) guidelines are based upon the best information available at the time of publication. They are designed to provide information and assist decision-making. They are not intended to define a standard of care and should not be construed as one. Neither should they be interpreted as prescribing an exclusive course of management.

- Variations in practice will inevitably and appropriately occur when providers take into account the needs of individual patients, available resources, and limitations unique to an institution or type of practice. Every healthcare professional making use of these guidelines is responsible for evaluating the appropriateness of applying them in the setting of any particular clinical situation.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The guideline and algorithms are designed to be adapted to individual facility needs and resources. The algorithm will serve as a guide that providers can use to determine best interventions and timing of care for their patients to optimize healthcare utilization. This should not prevent providers from using their own clinical expertise in the care of an individual patient. Guideline recommendations should facilitate, not replace, clinical judgment.

Although this guideline represents the state of the art practice on the date of its publication, medical practice is evolving and this evolution will require continuous updating of published information. New technology and more research will improve care in the future. The clinical practice guideline can assist in identifying priorities for research efforts and allocation of resources. As a result of implementing a more unified approach to COPD management, followed by data collection and assessment, new practice-based evidence may emerge.

To provide evidence-based action recommendations whenever possible, major clinical randomized controlled trials (RCTs) and other clinical trials published through November 2006 regarding pharmacotherapy interventions in COPD were reviewed. A series of large studies were near completion in late 2006 but had not been published as peer reviewed papers. These studies were conducted by the Towards a Revolution in COPD Health group (TORCH). The TORCH multi-national trial looks specifically at all-cause mortality (primary outcome) and secondarily at other health outcomes such as a decrease in the rate of COPD exacerbations. Another study conducted by the Understanding Potential Long-term Impacts on Function with Tiotropium (UPLIFT) group focuses on reducing the rate of decline of pulmonary function and is nearing completion. Once these studies are published in peer reviewed journals, they will be incorporated.

Goals and Outcomes

By implementing the guideline, providers will recognize the following:

- Respiratory assessment is an integral component of risk prediction in the primary prevention of lung diseases
- Treatment of COPD is an integral component of management of therapy in primary care
- Interventions identified are for modifying the risk for death, acute exacerbations, and progression of the disease and improving the patient's quality of life (QOL) and lung functionality

IMPLEMENTATION TOOLS

Clinical Algorithm
Pocket Guide/Reference Cards

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

End of Life Care
Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Management of COPD Working Group. VA/DoD clinical practice guideline for the management of outpatient chronic obstructive pulmonary disease. Washington (DC): Department of Veteran Affairs, Department of Defense; 2007. 138 p.

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 Aug (revised 2007)

GUIDELINE DEVELOPER(S)

Department of Defense - Federal Government Agency [U.S.]
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United States Government

GUIDELINE COMMITTEE

Management of Chronic Obstructive Pulmonary Disease Guideline Update Working Group

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Veterans Health Administration (VHA). Clinical practice guideline for the management of chronic obstructive pulmonary disease. Version 1.1a. Washington (DC): Department of Veterans Affairs (U.S.), Veterans Health Administration; 1999 Aug. 116 p.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Department of Veterans Affairs Web site.

Print copies: Department of Veterans Affairs, Veterans Health Administration, Office of Quality and Performance (10Q) 810 Vermont Ave. NW, Washington, DC 20420.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- VA/DoD clinical practice guideline for management of outpatient chronic obstructive pulmonary disease. Guideline summary. Washington (DC): Department of Veterans Affairs (U.S.); 2007. 31 p. Electronic copies: Available from the Department of Veterans Affairs Web site.
- VA/DoD clinical practice guideline for management of outpatient chronic obstructive pulmonary disease. Pocket guide. Washington (DC): Department of Veterans Affairs (U.S.); 2007. 2 p. Electronic copies: Available from the Department of Veterans Affairs Web site.

Print copies: Department of Veterans Affairs, Veterans Health Administration, Office of Quality and Performance (10Q) 810 Vermont Ave. NW, Washington, DC 20420.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on September 9, 1999. The information was verified by the guideline developer on January 10, 2000. The summary was updated by ECRI on May 6, 2001. This summary was updated by ECRI Institute on October 28, 2008.

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